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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,539	10/04/1999	LOUIS S. KUCERA	0044317U3	9782

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.

09/412,539

Applicant(s)

KUCERA et al.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 31, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☒ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: The amendment to claim 56 where the list of viruses includes HIV is not described in the specification. The specification is limited to HIV-1.

4. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached Advisory Action.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 56-71, 95, 96, and 101
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other: \_\_\_\_\_

*Brenda Coleman*  
BRENDA COLEMAN  
PRIMARY EXAMINER  
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### **ADVISORY ACTION**

Claims 56-71, 95, 96 and 101 are pending in the application.

The period for reply is extended to run THREE MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 must be timely filed to avoid abandonment of this application.

The amendment filed January 31, 2002 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will **not** be entered because: while the proposed cancellation of claim 101 would overcome the 35 § U.S.C. 112, first paragraph rejection of claim 101 in the previous office action, however, the amendment is not sufficient to overcome the 35 § U.S.C. 112, first paragraph rejection of claims 56-71 and 96.

- a) The proposed amendment to claims 56-71 and 96 are drawn to the treatment of HIV, HBV, herpes virus, influenza, respiratory syncytial virus, mumps, measles, and parainfluenza virus. There is no evidence of record that applicants' compounds have shown clinical efficacy. The specification is only speculative in the use of the compounds of Formula III for herpes viruses, influenza, respiratory syncytial virus, mumps, measles, and parainfluenza viruses. Additionally, there is

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not one species which exhibits anti-viral activity. The applicants' state that "an exemplary preferred compound of Formula III" is "3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine" as shown in the specification on page 13, lines 1-2. The applicants' further state that "examples 5 and 6 found on pages 21-23 of the specification illustrate how to make such a compound of Formula III. However, 3'-azido-3'-deoxy-5'-(3-dodecanamido-2-decyloxypropyl)-phosphothymidine and examples 5 and 6 are not within the genus of Formula III. The applicants' also stated that "the specification sets forth the efficacy of the compounds of Formula III in combating viral infection as shown on page 14, line 20 through page 15, line 8. However, the compounds tested, i.e. CP-128, CP-129, CP-130, CP-131, and INK-1 are also not within the genus of Formula III, but rather the genus of Formulae I and II.

- b) The proposed amendment to claims 56 and 95 would be sufficient to overcome the 35 § U.S.C. 112, second paragraph rejection of claims 56-71, 95, 96 and 101, however, the following new ground of objection would be necessary:

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Formula VII on pages 5 and 6.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman  
Primary Examiner AU 1624  
February 19, 2002